Draft 1 - Report on Review of NOP Accreditation
Submitted by Jim Riddle, Chair, NOSB Accreditation Committee
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I. Introduction:

Due to the fact that a Peer Review Panel has not been appointed by the USDA, the NOSB Accreditation Committee, at the suggestion of AMS/TMD Deputy Administrator Barbara Robinson, has conducted a review of the NOP's blank accreditation documents and accreditation program. The review has compared the materials provided against the requirements of the NOP Final Rule and ISO/IEC GUIDE 61 "General Requirements for Assessment and Accreditation of Certification/Registration Bodies".

The following documents, provided by the USDA's Audit Review and Certification (ARC) Branch, were reviewed:

1) ARC Instruction 1019 "National Organic Program – Accreditation for Organic Certification Organizations"
2) ARC Instruction 1019A "General Procedures for Receipt of NOP Application. Responsibility – ARC Branch"
3) ARC Instruction 1019B "Quality Systems Verification Program Auditors Report – Quality Control"
4) OMB NO. 0581-0191 (TM-10CG) "Application for Accreditation"
5) NOP-14.3 – "NOP Initial Accreditation Application Checklist" (10/24/01)
6) NOPComplianceChecklist01-31-02 "National Organic Program Compliance Audit Checklist"
7) NP 2036 WA "NOP Committee Meeting Minutes"
8) Letter to applicants for accreditation (not numbered)
9) "Decision on Accreditation" (not numbered)

II. Review of Documents:

1) ARC Instruction 1019 "National Organic Program – Accreditation for Organic Certification Organizations"

This document, issued by the Audit Review and Certification Branch, provides the basis for a Quality Manual. It does not, however, address fundamental ISO 61 requirements, including: a description of the organizational structure of the accreditation program, such as a chart showing lines of authority; procedures for disseminating and publishing program explanations; recordkeeping and document control; separation of auditing and decision-making functions; policies and procedures for the resolution of complaints; procedures for conducting internal audits; and the qualifications, training, and experience of all personnel involved in the accreditation process.

The document states that a "Program Review and Approval Committee" will "include representation from NOP, ARC, and an independent third party". Review of the NP 2036 WA "NOP Committee Meeting Minutes" documents shows that the Committee does not include an independent third party.

ARC Instruction 1019 states that "All decisions on accreditation will be based on recommendations of the Review and Approval Committee". There is no policy stating that members of the Committee must not have participated in the review of the applicant program. (As required by ISO 61: 3.2.2.f)

The document allows accreditation to be "granted prior to a site evaluation". While this is consistent with the NOP Final Rule, it is a violation of ISO Guide 61: 3.3.2.

According to the instruction document, "Committee members may elect to deny initial accreditation" for "failure to provide objective evidence of complete program implementation during the course of the initial site evaluation audit." It is widely suspected that some NOP accredited certifying agents have failed to fully implement all program requirements, yet they remain accredited.

The document states that "All accredited certifying agents must furnish reasonable security." This issue remains unresolved by the NOP, and certifying agents have been accredited without providing "reasonable security".

On the subject of "confidentiality", ARC Instruction 1019 states that "All materials submitted by applicants and maintained by the NOP or ARC Branch are available for public inspection and are subject to complete disclosure under the Freedom of Information Act. Any portion of the program documentation that the applicant considers proprietary must be identified at the time the information is submitted along with written justification why the documents should not be released to or reviewed by the public."

If all accreditation applicants were informed of the confidentiality policy stated above, then the collection of accreditation documents to comply with the current FOIA request should be greatly facilitated.

2) ARC Instruction 1019A "General Procedures for Receipt of NOP Application. Responsibility – ARC Branch"

This document contains a clear schematic and narrative flow chart followed by the ARC Branch for the processing of accreditation applications.

3) ARC Instruction 1019B "Quality Systems Verification Program Auditors Report – Quality Control"

This document contains a schematic and narrative flow chart followed by the ARC Branch for the review of accreditation documents. The schematic does not match up to the narrative, in that there is no box # 3. There appear to be 3 spelling errors in the narrative. Narrative item # 5 makes reference to "all required information as outline in ISO 61". Narrative item # 10 makes reference to a "Quality Systems Audit Report", which is a document not provided for this review.

4) OMB NO. 0581-0191 (TM-10CG) "Application for Accreditation"

This is the accreditation application form completed by all applicant certifying agents. It is consistent with the NOP Final Rule. It does not require applicants to submit "quality manuals", as required by ISO 61 and as referenced in ARC documents.

5) NOP-14.3 – "NOP Initial Accreditation Application Checklist" (10/24/01)

It is unclear if this is a draft or final document, as it does not appear to follow the ARC file naming protocol. There is no space to enter the name and/or file name of the applicant certifying agent. It is not clear if all items listed on the form are mandatory, or if some are optional, since, in the copy reviewed, some boxes are marked with an "X", some are marked "NA", and many are left unmarked.

All items appear in plain text, except for one item, which is in italics – "*procedures to monitor document control* (possible addition by NOP)". This item appears to indicate that while document control is not required by the NOP Final Rule, it may be added to comply with ISO 65 and ISO 61 requirements.

6) NOPComplianceChecklist01-31-02 "National Organic Program Compliance Audit Checklist"

The "Compliance Audit Checklist" begins with a box containing 7 definitions. None of the definitions match up with the definitions for the same terms in OFPA or in the NOP Final Rule.

It does not appear that the ARC file naming protocol was followed in the naming of this document.

The "Compliance Audit Checklist" closely mirrors the NOP Final Rule. It is the tool used by auditors during site evaluations to assess compliance. It is extremely comprehensive. Based on the structure of the document, it appears that the auditor's comments are entered in narrative fashion in the boxes marked "Auditor's Summary" that appear at the beginning of each section. The bulk of the text provides detailed instructions to the auditors.

Because the checklist follows the text of the Rule, auditors are instructed to ask how certifying agents identify and inform exempt and excluded operations that they are exempt or excluded, and that such operations must comply with applicable requirements of the NOP. While this may seem like a small point, it is unreasonable to require certifying agents to identify and inform exempt and excluded operation of the NOP requirements.

7) NP 2036 WA "NOP Committee Meeting Minutes"

As previously mentioned, the "Committee" shown on the document reviewed does not contain an independent third party member, as required by ARC Instruction 1019.

The remainder of the "Committee Meeting Minutes" form is blank, so it is difficult to assess whether NOP and ISO 61 requirements are being followed.

8) Letter to applicants for accreditation (not numbered)

This form letter, sent to all accredited certifying agents, is not numbered. As such, it does not follow the ARC file numbering protocol, and does not meet ISO 61 document control requirements. It summarizes NOP Final Rule requirements.

9) "Decision on Accreditation" (not numbered)

This decision form, sent to all accredited certifying agents, is not numbered. As such, it does not follow the ARC file numbering protocol, and does not meet ISO 61 document control requirements.

The decision form provides the certifying agent with general conditions for accreditation, but does not include detailed information about exactly which policies, procedures, standards, etc., must be changed to come into full compliance.

III. Review against ISO/IEC GUIDE 61 "General Requirements for Assessment and Accreditation of Certification/Registration Bodies"

The NOP Final Rule, 205.509, requires that the NOP accreditation program operate in accordance with ISO/IEC Guide 61. While the preliminary review of accreditation documents revealed that many requirements of ISO 61 are being met, sufficient information has not been provided to conduct a comprehensive review.

The primary areas of concern where the NOP accreditation program may or may not be in compliance with ISO Guide 61 include:

1) Providing sufficient explanation to applicants on accreditation requirements;
2) Enabling the participation of all parties significantly concerned in the content and functioning of the accreditation system;
3) Ensuring that each decision on accreditation is taken by a person or persons different from those who carried out the assessment;
4) Having a quality system and quality manual;
5) Getting involved, directly or indirectly, in the certification decision-making process;
6) Having policies and procedures for the resolution of complaints;
7) Having procedures for document control;
8) Establishing procedures for internal audits;
9) Maintaining a record keeping system;
10) Providing information on the relevant qualifications, training, and experience of all personnel involved in the accreditation process;
11) Conducting on-site evaluations before initial accreditation is granted; and
12) Promptly providing assessment reports to applicant certifying agents.

Shown below are selected excerpts from ISO/IEC GUIDE 61 "General Requirements for Assessment and Accreditation of Certification/Registration Bodies", with items of particular importance to the NOP accreditation program presented in **bold**:

* 2.1.1.3. The accreditation criteria which the competence of an applicant body is assessed shall be those outlined in the ISO/IEC Guides 40 and 62 or other normative documents relevant to the function performed. **If an explanation is required as to the application of these documents to a specific accreditation programme, it shall be** formulated by relevant and impartial committees or persons possessing the necessary technical competence, and **published by the accreditation body**.

* 2.1.2. Organization

The structure of the accreditation body shall be such as to give confidence in its accreditations. In particular, **the accreditation body shall**

e) have a documented structure which safeguards impartiality, including provisions to assure the impartiality of the operations of the accreditation body; this structure shall **enable the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the accreditation system;**

f) **ensure that each decision on accreditation is taken by a person or persons different from those who carried out the assessment;**

k) **have a quality system**, as outlined in 2.1.4., giving confidence in its ability to operate an accreditation system for certification / registration bodies;

l) **have policies and procedures that distinguish between accreditation and any other activities in which the accreditation body is engaged;**

o) ensure that activities of related bodies do not affect the confidentiality, objectivity or impartiality of its accreditations and **shall not offer or provide, directly or indirectly,**

1) **those services that it accredits others to perform,**

2) consulting services to obtain or maintain accreditation,

3) **services to design, implement or maintain a certification scheme (see note 3);**

p) **have policies and procedures for the resolution of complaints,** appeals and disputes received from bodies or other parties about the handling of accreditation or any related matters.

* 2.1.4.1. **The management of the accreditation body with executive responsibility for quality shall define and document its policy for quality, including objectives for quality and its commitment to quality.** The management shall ensure that this policy is understood, implemented and maintained at all levels of the organization.

* 2.1.4.2. **The accreditation body shall operate a quality system in accordance with the relevant elements of this Guide and appropriate to the type, range and volume of work performed. This quality system shall be documented and the documentation shall be available for use by the staff of the accreditation body.** The accreditation body shall ensure effective implementation of the documented quality system procedures and instructions. The accreditation body shall designate a person with direct access to its highest executive level who, irrespective of other responsibilities, shall have defined authority to

a) ensure that a quality system is established, implemented and maintained in accordance with this Guide;

b) report on the performance of the quality system to the management of the accreditation body for review and as a basis for improvement of the quality system.

* 2.1.4.3. **The quality system shall be documented in a quality manual** and associated quality procedures, and the quality manual shall contain or refer to at least the following:

d) **an organization chart showing lines of authority, responsibility and allocation of functions** stemming from the senior executive and, in particular, the relationship between those responsible for the assessment and those taking decisions regarding accreditation;

f) the policy and procedures for conducting management reviews;

g) **administrative procedures including document control;**

i) the policy and procedures for the recruitment and training of accreditation body personnel (including auditors) and monitoring their performance;

k) **its procedures for handling nonconformities and for assuring the effectiveness of any corrective actions taken;**

l) the policy and procedures for implementing the accreditation process, including

3) the procedures for assessing and accrediting applicants,

4) the procedures for surveillance and reassessment of accredited bodies;

m) **the policy and procedures for dealing with** appeals, **complaints** and disputes;

n) **the procedures for conducting internal audits based on the provisions of ISO 10011-1.**

* 2.1.5.2. **The accreditation body shall have procedures to**

c) **conduct reassessment** in the event of changes significantly affecting the activity and operation of the accredited body (such as change of ownership, changes in personnel or equipment), or **if analysis of a complaint or any other information indicates that the accredited body no longer complies with the requirements of the accreditation body.**

* 2.1.6.1. **The accreditation body shall conduct periodic internal audits** covering all procedures in a planned and systematic manner, to verify that the quality system is being implemented and is effective. The accreditation body shall ensure that

a) personnel responsible for the area audited are informed of the outcome of the audit;

b) corrective action is taken in a timely and appropriate manner;

c) the results of the audit are documented.

* 2.1.7.1. **The accreditation body shall document, update at regular intervals, and make available (through publications, electronic media or other means), on request,**

f) **information on procedures for handling complaints**, appeals and disputes;

* 2.1.8.1. **The accreditation body shall maintain a record system to suit its particular circumstances and to comply with existing regulations.** The records shall demonstrate that accreditation procedures have been effectively fulfilled, particularly with respect to application forms, assessment reports, and other documents relating to granting, maintaining, extending, reducing, suspending, or withdrawing accreditation. The records shall be identified, managed and disposed of in such a way as to ensure the integrity of the process and confidentiality of the information. The records shall be kept for a period of time so that continued confidence may be demonstrated for at least one full accreditation cycle, or as required by law.

* 2.2.1.2. **Information on the relevant qualifications, training and experience of each member of the personnel involved in the accreditation process shall be maintained by the accreditation body. Records of training and experience shall be kept up to date.**

* 2.2.1.3. **Clearly documented instructions shall be available to the personnel** describing their duties and responsibilities. These instructions shall be maintained up to date.

* 2.2.5.1. **Assessment personnel records**

a) name and address;

b) affiliation and position held in the organization;

c) educational qualifications and professional status;

d) **experience and training in each field of competence of the accreditation body;**

e) date of most recent updating of record;

f) **performance appraisal.**

* 2.6.2. The accreditation body shall

a) **keep a record of all appeals, complaints and disputes, and remedial actions relative to accreditation;**

b) take appropriate corrective and preventive action;

c) document the actions taken and assess their effectiveness.

* 3.1.1.1. A detailed description of the assessment and accreditation procedure, the **documents containing the requirements for accreditation, and documents describing the rights and duties of accredited bodies** shall be maintained up to date as specified in 2.1.7.1 and **shall be provided to applicants and accredited bodies.**

* 3.1.1.2. **The accreditation body shall require that a body**

f) **does not allow the fact of its accreditation to be used to imply that a product, process, system or person is approved by the accreditation body;**

* 3.1.1.3 When the desired scope of accreditation is related to a specific programme, any **necessary explanation shall be provided to the applicant.**

* 3.3.2. **The accreditation body shall witness fully the on-site activities of one or more assessments or audits conducted by an applicant body before an initial accreditation is granted** for any function requiring on-site activity by the applicant.

* 3.4.1. The accreditation body may adopt reporting procedures that suit its needs but, as a minimum, these procedures shall ensure that

c) **a report on the outcome of the assessment is promptly brought to the body's attention by the accreditation body,** identifying any nonconformity to be discharged in order to comply with all of the accreditation requirements;

d) **the accreditation body shall invite the body to comment on the report** and to describe the specific actions taken, or planned to be taken within a defined time, to remedy any nonconformity with the accreditation requirements identified during the assessment, and shall inform the body of the need for full or partial reassessment or whether a written declaration to be confirmed during surveillance will be considered adequate;

* 3.5.1. The accreditation body shall have an established documented programme, consistent with the accreditation granted, for carrying out periodic surveillance and reassessment at sufficiently close intervals to verify that its accredited body continues to comply with the accreditation requirements.

* NOTE 6. In most cases it is unlikely that a period greater than one year would satisfy the surveillance requirements of this clause.